guidance is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1817 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
211	Current good manufacturing practice for finished pharmaceuticals	0910–0139
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
801	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Quality System (QS) Regulation	0910–0073

Dated: September 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20472 Filed 9–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2232]

Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' This guidance describes FDA's intention with regard to enforcement of the Drug Supply Chain Security Act (DSCSA) provision requiring manufacturers to begin affixing or imprinting product identifiers on their products beginning November 27, 2017. This guidance finalizes the draft guidance issued on July 3, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency Guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–2232 for ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1) which established product tracing, product identifier, authorized trading partner and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Among its provisions, section 582 of the FD&C Act requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers were required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017. Failure to comply with this and other requirements of section 582 is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and subject to enforcement action under the FD&C Act.

In the **Federal Register** of July 3, 2017 (82 FR 30868), FDA issued a notice announcing the availability of the draft version of this guidance. As described in the guidance, in the years since the passage of DSCSA, FDA had received comments and feedback from manufacturers and other trading partners expressing concern with industry-wide readiness for implementation of the DSCSA provision requiring manufacturers to begin putting product identifiers on their products by November 27, 2017. Given the implementation challenges that industry has encountered, FDA recognized that some manufacturers would need additional time beyond November 27, 2017, to ensure that their products bear a product identifier as required by the DSCSA. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to packages or homogenous cases of product that are packaged before November 27, 2018. This includes packages and homogenous cases of product that are packaged by a manufacturer on or after November 27, 2017. The comment period for the draft guidance ended September 1, 2017. FDA received 19 comments on the draft guidance.

FDA made several changes to the guidance. We streamlined the guidance to remove information that is portions of the draft version of this guidance because they were repetitive of the information in the final guidance for industry entitled, ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' In addition, FDA removed the language in the draft version of this guidance on wholesale distributor and dispenser responsibilities to ensure product purchased from repackagers after November 27, 2018, is affixed or imprinted with a product identifier. Finally, FDA removed the recommendations in the draft version of this guidance related to the documentation for determining when a product without a product identifier was introduced in a transaction into commerce by a manufacturer. The topic of documentation is addressed in the final grandfathering policy guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov*.

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20444 Filed 9–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3175]

Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers.'' This draft guidance intends to clarify questions relating to product identifiers that are required by the Federal Food, Drug, and Cosmetic Act